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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,596	02/19/2002	Rajesh Bhikhu Parekh	9195-082	7657
20583	7590	10/05/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 10/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/079,596	<b>Applicant(s)</b> PAREKH ET AL.	
	<b>Examiner</b> Susan Ungar	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. Claims 1-31 are pending in the application and are currently under prosecution.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121.

**Group 1 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/diagnosis for determining the stage of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 2 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/diagnosis for determining the severity of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 3 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/diagnosis for identifying a subject at risk of developing hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 4 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/diagnosis for monitoring the effect of therapy administered to a subject having hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 5 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/prognosis for determining the stage of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's

convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 6 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/prognosis for determining the severity of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 7 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/prognosis for identifying a subject at risk of developing hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 8 consists of  $1.9 \times 10^{243}$  inventions.**

Claims 1-6 are drawn to a method for screening/prognosis for monitoring the effect of therapy administered to a subject having hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 141 distinct features. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $141! = 1.9 \times 10^{243}$ . It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. Claims 2 and 3 will be examined as they are drawn to the elected invention.

**Group 9 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/diagnosis for determining the stage of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 10 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/diagnosis for determining the severity of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is

required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 11 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/diagnosis for identifying a subject at risk of developing hepatoma, classified in Class 435, subclass 4, 7.1.

It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 12 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/diagnosis for monitoring the effect of therapy administered to a subject having hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 13 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/prognosis for determining the stage of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of

combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 14 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/prognosis for determining the severity of hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 15 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/prognosis for identifying a subject at risk of developing hepatoma, classified in Class 435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 16 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 7-9 are drawn to a method for screening/prognosis for monitoring the effect of therapy administered to a subject having hepatoma, classified in Class

435, subclass 4, 7.1. It is noted that the claims are drawn to analyzing at least one of 27 distinct features. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single feature or a specific combination of features to be analyzed. .

**Group 17 consists of 27 inventions.**

Claims 10-11 and 12 as it is are drawn to an antibody that binds to one of 27 features method for screening/prognosis for monitoring the effect of therapy administered to a subject having hepatoma, classified in Class 540, subclass 387.1. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect an antibody specific for a single feature claimed.

**Group 18 consists of  $1.1 \times 10^{28}$  inventions.**

Claim 12 is drawn to a preparation comprising at least one of the 27 isoforms claimed in claim 12, classified in Class 530 subclass 350. It is noted that the claims are drawn to a preparation comprising at least one of 27 distinct isoforms. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single isoform or a specific combination of isoforms to be analyzed.

**Group 19 consists of 27 inventions.**

Claims 13-14 are drawn to a method of treating/preventing hepatoma comprising administering an antibody of claim 10, classified in Class 424

subclass 130.1. It is noted that the claims are drawn to methods of treating with 27 distinct antibodies. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect an antibody against a single antigen for examination.

**Group 20 consists of 27 inventions.**

Claim 15 is drawn to a method of treating/preventing hepatoma comprising administering a nucleic acid encoding one of the 27 HPIs claimed in claim 15, classified in Class 536 subclass 23.1. It is noted that the claims are drawn to methods of treating with 27 distinct nucleic acids. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a nucleic acid encoding a single HPI for examination.

**Group 21 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 16-17 are drawn to method of treating/preventing hepatoma comprising administering a nucleic acid that inhibits the expression of one or more of the 27 HPIs claimed in claim 16, classified in Class 536 subclass 23.1. It is noted that the claims are drawn to methods of treating with 27 distinct nucleic acids inhibitors. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single inhibitor or a specific combination of inhibitors for examination.

**Group 22 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 16-17 are drawn to method of treating/preventing hepatoma comprising administering a nucleic acid that inhibits the function of one or more of the 27

HPIs claimed in claim 16, classified in Class 536 subclass 23.1. It is noted that the claims are drawn to methods of treating with 27 distinct nucleic acids inhibitors. It is further noted that by factorial analysis,  $n! = \text{number of combinations}$ , the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single inhibitor or a specific combination of inhibitors for examination.

**Group 23 consists of 27 inventions.**

Claims 18 is drawn to method of screening for agents that interact an HPI, classified in Class 435, subclass 4, 7.1 It is noted that the claims are drawn to methods of treating with screening 27 HPIs. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single HPI for examination.

**Group 24 consists of 27 inventions.**

Claims 19 is drawn to an in vitro cell method of screening for agents that modulate the expression of an HPI, classified in Class 435, subclass 4, 7.1 It is noted that the claims are drawn to methods of screening 27 HPIs. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single HPI for examination.

**Group 25 consists of 27 inventions.**

Claims 19 is drawn to an in vitro cell method of screening for agents that modulate the activity of an HPI, classified in Class 435, subclass 4, 7.1 It is noted that the claims are drawn to methods of screening 27 HPIs. It is noted for Applicant's convenience that this is **not** an election of species requirement,

but rather Applicant is required to specify and elect a single HPI for examination.

**Group 26 consists of 27 inventions.**

Claims 20-21 are drawn to an in vivo method of screening for agents that modulate the expression of an HPI, classified in Class 424, subclass 130.1. It is noted that the claims drawn to methods of screening 27 HPIs. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single HPI for examination.

**Group 27 consists of 27 inventions.**

Claims 20-21 are drawn to an in vivo method of screening for agents that modulate the activity of an HPI, classified in Class 424, subclass 130.1. It is noted that the claims are drawn to methods of screening 27 HPIs. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single HPI for examination.

**Group 28 consists of 27 inventions.**

Claims 22-24 are drawn to an in vitro cell-free method of screening for agents that modulate the activity of an HPI, classified in Class 435, subclass 4, 7.1 It is noted that the claims are drawn to methods of screening 27 HPIs. It is noted for Applicant's convenience that this **is not** an election of species requirement, but rather Applicant is required to specify and elect a single HPI for examination.

**Group 29 consists of one invention**

Claims 25-29 are drawn to an isolated nucleic acid molecule that hybridizes to HPI-13, a vector and host cell comprising said molecule, classified in Class 536, subclass 23.1.

**Group 30 consists of one invention**

Claims 25-29 are drawn to an isolated nucleic acid molecule that hybridizes to HPI-21, a vector and host cell comprising said molecule, classified in Class 536, subclass 23.1.

**Group 31 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 30-31 are drawn to method of screening/diagnosis of hepatoma for monitoring the effect of an anti-hepatoma drug or therapy, classified in Class 536 subclass 23.1. It is noted that the claims are drawn to methods of screening/diagnosis with probes to 27 distinct nucleic acids. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is required to specify and elect a single probe or a specific combination of probes for examination of the claimed assay.

**Group 32 consists of  $1.1 \times 10^{28}$  inventions.**

Claims 30-31 are drawn to method of screening/prognosis of hepatoma for monitoring the effect of an anti-hepatoma drug or therapy, classified in Class 536 subclass 23.1. It is noted that the claims are drawn to methods of screening/diagnosis with probes to 27 distinct nucleic acids. It is further noted that by factorial analysis,  $n!$ =number of combinations, the number of combinations claimed is  $27! = 1.1 \times 10^{28}$ . It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather Applicant is

required to specify and elect a single probe or a specific combination of probes for examination of the claimed assay. Claim 31 will be examined as it is drawn to the elected invention.

3. It is noted that claim 1 of Groups 1-8 is a linking claim.

Claim 1 recited in each of Groups 1-8 above, links inventions (A-C). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.

For each of the inventions of Groups 1-8, restriction to one of the following is also required under 35 USC121.

(A) the claimed method in combination with an assay for Hepatitis B

(B) the claimed method in combination with an assay for Hepatitis C

(C) the claimed method in combination with an assay for Hepatitis B and C

For each of the inventions of Group 1 and (A)-(C) above, restriction to one of the following is also required under 35 USC121. Therefore, election is

required of one of the inventions of Group 1 **and** one of inventions (A)-(C). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of the inventions of Group 1, **and** one of inventions (A)-(C) above. Claims 1-6 will be examined as they are drawn to the specifically elected invention.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions 17-18, 29, 30 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 1-16, 19-28, 31-32 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 17 and 1-16, 19, 28 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product claimed can be used in a materially different process such as production of anti-idiotypic antibodies.

The inventions of Groups 18 and 1-16, 23-28 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see

*MPEP* § 806.05(h)]. In the instant case the polypeptide products claimed can be used in a materially different process such as production of antibodies.

The inventions of Group 29 and 20-22, 31-32 as they are drawn to HPI-13 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the HPI-13 product claimed can be used in a materially different process such as production of the encoded polypeptide.

The inventions of Group 30 and 20-22, 31-32 as they are drawn to HPI-21 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the HPI-21 product claimed can be used in a materially different process such as production of the encoded polypeptide.

The inventions of Groups 29 and 30 are not at all related to Groups 1-16, 19, 23-28 or to Groups 20-22, 31-32 as they are drawn to HPIs other than 13 and 21 because the inventions of Groups 29 and 30 are not used in any of the methods of Groups 1-16, 19, 23-28 or to Groups 20-22, 31-32 as they are drawn to HPIs other than 13 and 21.

The inventions of Group 17 and 1-16, 20-8, 31-32 are not at all related because the inventions of Group 17 is not used in any of the methods of Groups 1-16, 20-8, 31-32.

The inventions of Groups 18 and 19-22, 31-32 are not at all related because the inventions of Group 17 are not used in any of the methods of Groups 19-22, 31-32.

Further, the inventions of Groups 1-16, 18, 21-22, 31-32 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP . 806.05(c)). In the instant case, the patentability of the combinations do not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for or treating different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

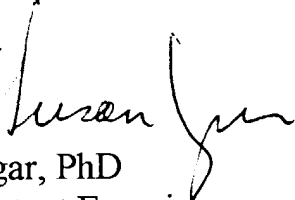
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application

Art Unit: 1642

in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.

Susan Ungar, PhD  
Primary Patent Examiner  
September 14, 2004